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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/081,969	02/22/2002	Cheng Cheng	4-31704A/GTI	4496
1095	7590	02/24/2004	EXAMINER	
THOMAS HOXIE NOVARTIS, CORPORATE INTELLECTUAL PROPERTY ONE HEALTH PLAZA 430/2 EAST HANOVER, NJ 07936-1080			MARVICH, MARIA	
		ART UNIT	PAPER NUMBER	
		1636		

DATE MAILED: 02/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

SMA

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/081,969	CHENG ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Maria B Marvich, PhD	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 01 December 2003.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-11, 13-14, 16-45, 47-51, 58-59 and 62-66 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) 1-6,8-11,13,14,16-45,47-51,58 and 59 is/are allowed.
- 6) Claim(s) 7 and 62-64 is/are rejected.
- 7) Claim(s) 65 and 66 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 12/1/03; 4/11/03.
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_.

## **DETAILED ACTION**

This office action is in response to an amendment filed 12/1/03. Claims 12, 15, 46, 52-57 and 60-61 have been cancelled. Claims 7-9, 16-17, 39, 42-43, 62 and 64 have been amended. Claims 1-11, 13-14, 16-45, 47-51, 58-59 and 62-66 are pending in the instant application.

An IDS filed 12/1/03 has been identified and the documents considered. The signed and initialed PTO Form 1449 has been mailed with this action. Subsequently, an IDS filed 4/11/03 has been identified in the file. The documents on this IDS have been considered but the documents have been crossed out as the IDS filed 4/11/03 is a duplicate of the IDS filed 12/1/03. There is a new rejection herein and therefore the rejection is non-final.

### ***Specification***

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. Oncolytic Adenoviral Vectors is not descriptive of the complexity of the instant invention.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 is vague and indefinite in that the metes and bounds of “or the corresponding functions in other adenoviral serotypes” are unclear. It is unclear whether the recombinant viral vector comprises the deletion **or** corresponding functions in other Adenovirus or alternatively, the deletion is of the nucleotides 103-551 **or** in the corresponding function. Furthermore, it is unclear as written to what “corresponding function” refers. It would be remedial to recite “or a deletion in nucleotides encoded by corresponding regions of other Adenovirus serotypes”. **This is a new rejection.**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 62-64 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new rejection. This is a new matter rejection.**

Claims 62-64 recite the limitation that the recombinant viral vector comprises “a heterologous transcriptional regulatory sequence operably linked to a coding region of a gene that is essential for replication of said vector”. The disclosure only teaches operably linking E1A, a gene required for replication, to E2F and osteocalcin promoters. The disclosure does not provide literal support for the inclusion of the limitation that the gene essential for replication of the vector is operably linked to any heterologous transcriptional regulatory sequence.

***Conclusion***

Claims 1-6, 8-11, 13-14, 16-45, 47-51, 58-59 are allowed.

Claims 7 and 62-64 are rejected.

Claims 65-66 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B Marvich, PhD whose telephone number is (571)-272-0774. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, PhD can be reached on (571)-272-0781. The Central Fax number for official documents is (703)-872-9305. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maria B Marvich, PhD  
Examiner  
Art Unit 1636

*Gerry Leffers*  
**GERRY LEFFERS**  
**PRIMARY EXAMINER**

February 12, 2004